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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

Appl. No.	:	10/021,622
Applicant(s)	:	Paul F. Laeseke et al.
Filed	:	December 12, 2001
Title	:	Cauterizing Biopsy System
TC/A.U.	:	3736
Examiner	:	Charles A. Marmor, II
Docket No.:	:	960296.98636

APPELLANT'S BRIEF ON APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants, Laeseke, et al, having filed a timely Notice of Appeal in the above-identified patent application, hereby submit this brief.

I. REAL PARTY IN INTEREST

The present application is assigned to the Wisconsin Alumni Research Foundation.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 5 – 8 and 10 are currently pending in the subject patent application and stand finally rejected. Claims 1 – 4, 9, and 11 – 20 have been withdrawn from consideration.

IV. STATUS OF AMENDMENTS

In response to a final office action, an amendment was filed on July 18, 2005. In an advisory action dated October 14, 2005, the amendments were denied entry as raising new issues.

V. SUMMARY OF THE INVENTION

The primary risk associated with biopsy of organs such as the liver is bleeding after the removal of the needle from the patient. Although bleeding occurs in a small number of patients, complications arising from the bleeding are severe and can lead to death. A secondary risk of biopsy procedures is the risk of the biopsy needle "seeding" cancer cells into other tissues and the bloodstream as the needle is withdrawn, resulting in the highly undesirable spread of cancer cells. It is extremely important when performing a biopsy in an organ, therefore, both to limit bleeding and to limit spread of cells to surrounding the tissue, such that a biopsy can be reliably used to cure the underlying problem rather than to exacerbate it.

The invention is a biopsy needle assembly including a shaft sized and dimensioned for insertion percutaneously through the skin of a patient and having a stylet with an electrically conductive surface that is adapted to be exposed to tissue. A radio frequency electrical source is coupled to the conductive surface and can be selectively activated to cauterize the tissue in the insertion path. The biopsy needle, includes a sampling means for removal of a tissue sample, and inter-fits with and is guided by the introducer shaft. The biopsy needle samples the tissue, and is guided through the shaft to remove the sample. After the sample is removed, the cauterizing power source is energized, and the insertion path is cauterized as the shaft is removed from the testing site.

The invention, therefore, provides a biopsy needle assembly that includes a means for cauterizing the insertion path to limit the primary risk associated with biopsy procedures of

organs, specifically bleeding. In addition, the assembly provides a shaft that allows a biopsy sample to be removed with minimal interaction between the sample and the surrounding tissue, thereby limiting the possibility of "seeding" of cells. Cauterizing the path after the sampling further reduces the possibility of "seeding". The present invention, therefore, provides a substantial and important improvement over prior art biopsy devices, and substantially decreases the possibility of detrimental effects of biopsy procedures.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Is claim 5 anticipated by Roberts, U.S. Patent 6,261,242, under 35 U.S.C. Section 102(e)?

B. Are claims 5 – 8 and 10 unpatentable over Roberts in view of Lennox, U.S. Patent 5,122,137?

VII. ARGUMENT

A. Is claim 5 anticipated by Roberts, U.S. Patent 6,261,242, under 35 U.S.C. Section 102(e)?

a. Rejection under 35 U.S.C. Section 102(e). Claim 5 recites a biopsy needle assembly including an introducer shaft and a biopsy needle. The introducer shaft is sized for percutaneous insertion into a patient along an insertion path to a biopsy site. The end to be located at the biopsy site includes an electrically conductive stylet that is adapted to be exposed to tissue, and which communicates with a radio frequency cauterizing electrical source. The biopsy needle interfits with and is guided by the introducer shaft, and includes a biopsy needle having a sampling means for removal of tissue. A large area electrode completes a circuit through the radio frequency cauterizing electrical source with the electrically conductive surface allowing cauterization of the insertion path as the biopsy needle is withdrawn.

Referring to paragraph 6 of the application as filed, the stylet is discussed as a "sharp rod". Referring also to paragraph 34, the stylet is again described as "rod-shaped ... having a sharpened end".

The Examiner, referring to Figs. 4a through 4c, asserts that Roberts teaches a biopsy sampler including an introducer shaft 50 having an electrically conductive surface 22 on a conductive stylet. In the comments associated with the advisory action, the Examiner cites two definitions for percutaneous: "passed, done, or effected through the skin" and "effected or performed through the skin". Based on these definitions, the Examiner asserts that "percutaneous" could mean "through a port or incision in the skin of the abdominal region", and suggests that the device disclosed by Roberts could be inserted through such an incision. The Examiner further asserts that a stylet is merely a "surgical probe", and therefore that elements 12 and 134 of the Roberts reference are each "stylets".

b. The Roberts Reference.

Referring to Figs. 1 – 3, Roberts discloses a biopsy sampler 10 that includes two basic parts: a cauterizing sheath 12 and a resecting device 14. The resecting device 14 includes a forceps 30 for taking a biopsy sample. Electrodes 22a and 22b are provided on the sheath 12, and are connected to an RF generator providing an energy source for cauterizing tissue with an electrode.

Referring to Figs. 4a through 4c and the associated description at column 5, line 51 through column 6, line 36, use of the biopsy sampler 10 is described. The biopsy sampler is shown inserted into an endoscope 50, which is inserted through a pre-existing body cavity in the patient, here specifically a colon 48. After a sample is retrieved with forceps 30, the electrodes cauterize the biopsy site and the entire biopsy assembly 10 is then retracted through or with the endoscope.

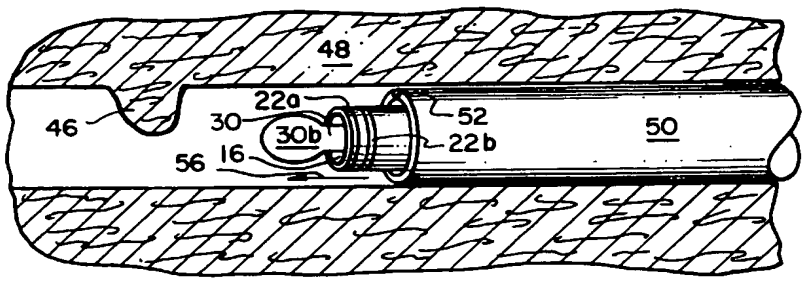

FIG. 4b

c. The Roberts Reference does not Anticipate Claim 5.

Based on the discussion above, it is clear that there are a number of substantial differences between the invention as recited in claim 5 and the biopsy sampler disclosed in the Roberts reference. The element equated with the introducer shaft by the Examiner, element 50, for example, is not part of a biopsy assembly at all. Rather, the cited component is an endoscope, a component entirely separate from the biopsy system and having an entirely separate purpose. The conductive surface, electrodes 22a and 22b, moreover, are not provided at a first end of the endoscope 50, but on a separate component, sheath 12. Sheath 12 is not connected to the endoscope in any way, but rather is designed to move freely and independently from the endoscope.

The biopsy assembly 10 and endoscope 50, moreover, are not inserted percutaneously, through the skin, but into a pre-existing body cavity. The specification neither discusses nor suggests percutaneous insertion, and the biopsy assembly 10 includes no element that would allow the device to be inserted in this way. The Examiner's assertion that percutaneous could mean "through a port or incision in the abdomen", moreover, is not supported by either the Roberts reference itself, or the definitions cited by the Examiner. Insertion through an incision in the abdomen is clearly not insertion through the skin, but through the absence of skin.

Neither the biopsy assembly 10 nor the combination of the biopsy assembly 10 and endoscope 50, moreover, provides any element equivalent to a stylet. A "stylet" as defined

by Webster's New Universal Unabridged Dictionary, Barnes & Noble, 1996, is "a stiletto or dagger" or "any similar sharp pointed instrument". As discussed in the specification, a stylet is as a component that includes a sharpened end. Whether relying on a dictionary meaning or on a meaning construed from the specification, therefore, the term "stylet" must mean an elongate object having a sharpened end.

Since the endoscope 50 and biopsy sampler in the Roberts reference are inserted through the colon 48, there is, moreover, no insertion path into the body to be cauterized. Since the electrodes are removed either with or through the endoscope, moreover, the electrodes could not be used to cauterize an insertion path if, in fact, such a path existed.

Roberts, therefore, does not recite all of the elements of claim 5, and cannot anticipate claim 5. The device disclosed by Roberts, moreover, does not provide the advantages of the present invention, and particularly cannot be used to limit the seeding of cancer cells when inserting a probe percutaneously, as discussed above. In view of these facts, the Appellants respectfully request that the rejection of claim 5 under 35 U.S.C. Section 102(e) be overturned.

B. Are claims 5 – 8 and 10 unpatentable over Roberts in view of Lennox, U.S. Patent 5,122,137?

a. Rejection under 35 U.S.C. Section 103. Claims 5 – 8 and 10 were also rejected under 35 U.S.C. Section 103 as unpatentable over Roberts in combination with Lennox.

Independent claim 5 is discussed above. Independent claim 10 recites a biopsy needle assembly including an introducer shaft sized for percutaneous insertion into a patient along an insertion path to locate the first end at a biopsy site. A first end of the shaft includes an electrically conductive surface adapted to be exposed to tissue, and connected with a radio frequency cauterizing electrical source. A biopsy needle interfits with and is guided by the introducer shaft, and includes a sampling means for removal of a tissue sample before

cauterization of the insertion path using the electrically conductive surface. A temperature sensor is positioned at the electrically conductive surface.

Here, the Examiner asserts that Roberts teaches an introducer shaft 12 including an electrically conductive surface 22, a biopsy needle 14 including a sampling means 30, and a stylet interfitted with the shaft, referencing Fig. 8b. Lennox is cited for disclosing a conductive stylet with a rounded tip (claim 6) and a temperature sensor disposed on the electrically conductive surface (claim 10).

The Examiner further asserts that it would be obvious to "withdraw a biopsy needle from an introducer shaft similar to that of Roberts after a biopsy sample is taken and to then insert a conductive stylet similar to that of Lennox into the introducer shaft in order to cauterize and coagulate the biopsy track as the introducer shaft is withdrawn from the patient, so as to prevent tumor seeding, hemorrhage, and leakage, while providing an indirect means of measuring and controlling the temperature". The Examiner, however, cites no passage in either reference to support this suggestion.

b. The Roberts and Lennox References. As discussed above, Roberts discloses a biopsy sampler assembly 10 that is inserted into a colon 48 through an endoscope 50. The biopsy sampler 10 includes an outer sheath 12 having electrodes 22a and 22b provided on an outer surface, and a resecting device 14, provided inside of the sheath 12. In use, the biopsy sampler is inserted into the endoscope 50. After a sample is retrieved with forceps 30, the electrodes cauterize the biopsy site and the entire biopsy assembly 10 is then retracted either through the endoscope or with the endoscope.

Lennox discloses a temperature-controlled RF coagulation device including a sensor for modulating the RF voltage to adjust temperature. The RF coagulation device and sensor are shown incorporated in a number of different types of medical devices including an RF probe, a needle probe, a catheter, a guidewire probe, and a forceps probe.

c. The Combination of Roberts and Lennox Does Not Render Claims 5 – 8 and 10 Obvious.

As noted above, the Examiner asserts that it would have been obvious at the time the invention was made to "withdraw a biopsy needle from an introducer shaft similar to that of Roberts after a biopsy sample is taken and then insert a conductive stylet similar to that of Lennox into the introducer shaft in order to cauterize and coagulate the biopsy track as the introducer shaft is withdrawn from the patient, so as to prevent tumor seeding, hemorrhage, and leakage, while providing an indirect means of measuring and controlling the temperature". Neither of the cited references, however, suggest such an operation.

As described above, Roberts discloses a biopsy assembly 10 that is inserted through a pre-existing cavity in the patient, and through an endoscope. Roberts, therefore, does not suggest a need for a conductive stylet or a need to cauterize an insertion path. Roberts, rather, avoids the need for these elements by inserting the biopsy assembly into the colon and through an endoscope, therefore avoiding both the need for a sharpened element to pierce the skin and the creation of an insertion path that would require cauterization. As a result, it is not necessary, and indeed not desirable, to include a sharp element to pierce the skin for insertion, and the only cauterization required and discussed is cauterization of the biopsy site.

Roberts, moreover, includes an electrode for providing cauterization of the biopsy site. There is, therefore, no motivation to modify Roberts to insert another electrode device as suggested by the Examiner. In fact, in the background section, Roberts discusses the disadvantages of using separate biopsy and cauterizing elements (see column 1, lines 19 – 32). Rather than suggesting the construction discussed by the Examiner, therefore, Roberts teaches away from such a construction.

Lennox discloses a method for treating tissue using an RF power source, but does not discuss any particular method for performing a biopsy. The only equipment shown that is suitable for use in a biopsy procedure is the forceps of Figs. 7 and 8. These forceps each

include RF electrodes embedded in the tips of the forceps to provide coagulation or cauterization. Therefore, it is clear that the forceps are constructed to include the elements necessary to cauterize tissue. Lennox, therefore, does not suggest inserting a biopsy tool, removing the biopsy tool, and replacing the biopsy tool with a cauterizing tool. Rather, Lennox suggests removing and cauterizing tissue with a single tool.

Neither of the cited references, moreover, discusses cauterization of an insertion path to avoid tumor seeding or to minimize bleeding. These elements are only discussed in the Appellants' application. Clearly, the cited motivation to combine Roberts and Lennox, therefore, is not found within either of the cited references, but impermissibly from within the Appellants' disclosure.

The cited references therefore fail to provide all of the elements of the rejected claims. Moreover, the cited references do not provide any suggestion or motivation to combine elements as suggested by the Examiner. It is therefore not obvious to combine the references as asserted in the Office Action, and the Appellants respectfully request that the rejection of claims 5 – 8 and 10 under 35 U.S.C. Section 103 be overturned.

VIII. CONCLUSION

Claim 5 stands rejected under 35 U.S.C. Section 102(e) as anticipated by Roberts. Claims 5 – 8 and 10 stand rejected under under 35 U.S.C. Section 103 as unpatentable over Roberts in combination with Lennox.

The rejection under 35 U.S.C. Section 102(e) is improper because Roberts fails to disclose all of the elements recited in claim 5. The rejection under 35 U.S.C. Section 103 is improper because the cited references fail to disclose all of the elements of the claims, and further because no proper motivation to combine these references has been shown. Therefore, the Appellants respectfully request that the rejection of claims 5 – 8 and 10 be reversed.

Respectfully submitted,

Paul F. Laeseke et al.

Dated: January 17, 2006

By: 

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APPENDIX A

5. A biopsy needle assembly comprising:

an introducer shaft having a first and second end, and sized for percutaneous insertion into a patient along an insertion path to locate the first end at a biopsy site, the first end having an electrically conductive surface adapted to be exposed to tissue and communicating by means of an insulated conductor to the second end to connect with a radio frequency cauterizing electrical source;

a large area electrode adapted to contact the patient without production of cauterizing temperatures to complete a circuit through the radio frequency cauterizing electrical source with the electrically conductive surface of the introducer shaft through a patient; and

a biopsy needle interfitting with the introducer shaft to be guided thereby, the biopsy needle including a sampling means for removal of a tissue sample before cauterization of the insertion path using the electrically conductive surface;

wherein the electrically conductive surface is a conductive stylet having a first end supported by the introducer shaft.

6. The biopsy needle assembly of claim 5 wherein the conductive stylet has a rounded tip.

7. The biopsy needle assembly of claim 5 wherein the introducer shaft is a hollow tube and wherein the insulated conductor is provided by a portion of the conductive stylet fitting within the hollow tube.

8. The biopsy needle assembly of claim 5 wherein a shaft portion of the conductive stylet includes an outer insulating covering to provide the insulated conductor.

10. A biopsy needle assembly comprising:

an introducer shaft having a first and second end, and sized for percutaneous insertion into a patient along an insertion path to locate the first end at a biopsy site, the first end having an electrically conductive surface adapted to be exposed to tissue and communicating by means of an insulated conductor to the second end to connect with a radio frequency cauterizing electrical source;

a large area electrode adapted to contact the patient without production of cauterizing temperatures to complete a circuit through the radio frequency cauterizing electrical source with the electrically conductive surface of the introducer shaft through a patient; and

a biopsy needle interfitting with the introducer shaft to be guided thereby, the biopsy needle including a sampling means for removal of a tissue sample before cauterization of the insertion path using the electrically conductive surface;

further including a temperature sensor positioned at the electrically conductive surface.

EVIDENCE APPENDIX

No additional evidence is being presented.

RELATED PROCEEDINGS APPENDIX

There are no related proceedings.